

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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21 CFR Part 74

[Docket No. 99C-1455]

Listing of Color Additives for Coloring Sutures; D&C Violet No. 2; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

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SEP 26 18:49

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of August 29, 2000 (65 FR 46342), for the final rule that appeared in the **Federal Register** of July 28, 2000, and that amended the color additive regulations to provide for the safe use of D&C Violet No. 2 as a color additive in absorbable sutures prepared from homopolymers of glycolide for general surgery. The agency also revised the nomenclature "polyglactin 910 (glycolic-lactic acid polyester)" to the generic nomenclature "copolymers of 90 percent glycolide and 10 percent L-lactide."

DATES: Effective date confirmed: August 29, 2000.

FOR FURTHER INFORMATION CONTACT: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3089.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 28, 2000 (65 FR 46342), FDA amended the color additive regulations in 21 CFR 74.3602 *D&C Violet No. 2* to provide for the safe use of D&C Violet No. 2 as a color additive in absorbable sutures prepared from homopolymers of glycolide for general surgery. The agency also revised the nomenclature

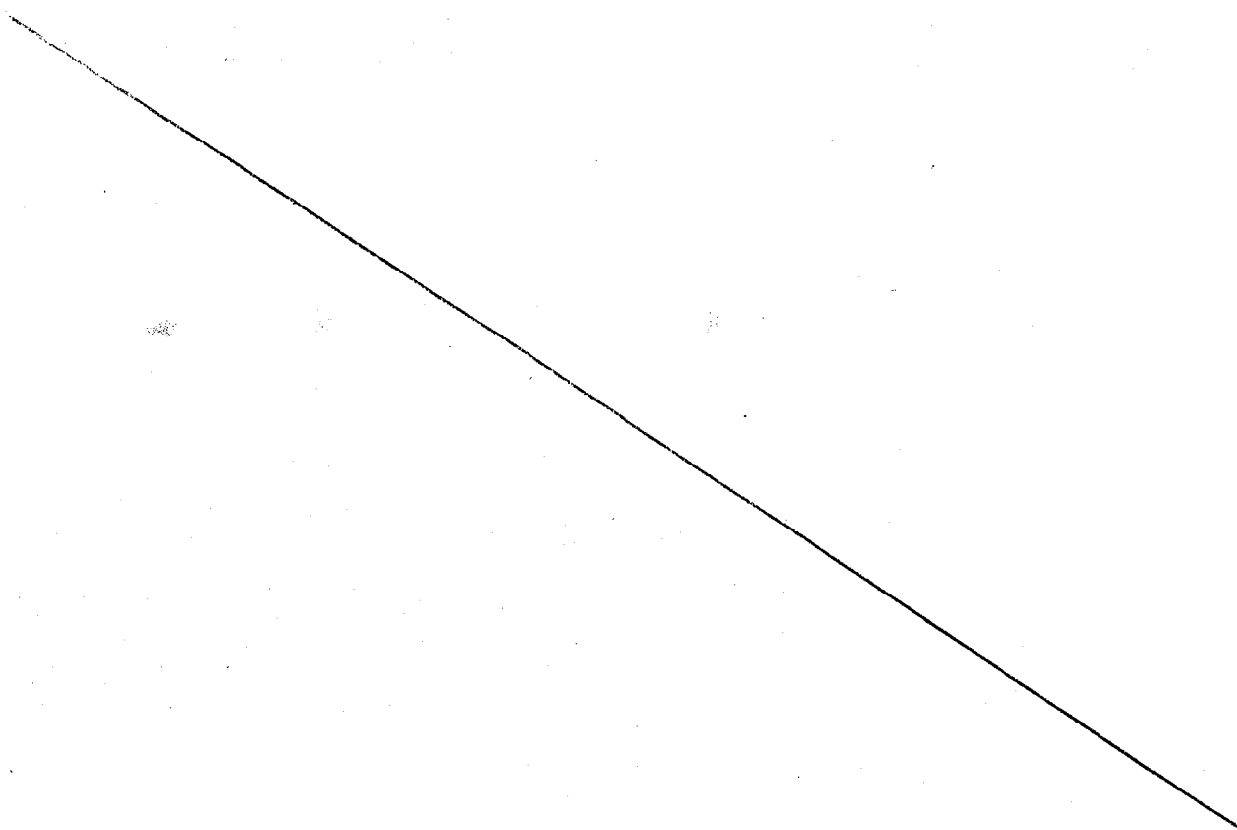
“polyglactin 910 (glycolic-lactic acid polyester)” to the generic nomenclature “copolymers of 90 percent glycolide and 10 percent L-lactide.”

FDA gave interested persons until August 28, 2000, to file objections or requests for a hearing. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA finds that the effective date of the final rule that published in the **Federal Register** of July 28, 2000, should be confirmed.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs, Foods, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of



Food and Drugs (21 CFR 5.10), notice is given that no objections or requests for a hearing were filed in response to the July 28, 2000, final rule. Accordingly, the amendments issued thereby became effective August 29, 2000.

Dated: September 21, 2000



William K. Hubbard,
Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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